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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 09/297,652 | 07/08/1999 | RICHARD EDWARD THOMAS | MJ-001USCPA | 1100 |

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BOSTON, MA 02109

EXAMINER

BADIO, BARBARA P

| ART UNIT | PAPER NUMBER |
|----------|--------------|
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1616

DATE MAILED: 09/01/2004

#34

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/297,652

Applicant(s)

THOMAS, RICHARD EDWARD

Examiner

Barbara P. Badio, Ph.D.

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-46 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-46 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on ____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) ____.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). ____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

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Supplemental First Office Action on the Merits of a RCE

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on June 17, 2003 has been entered.

2. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claim Rejections - 35 USC § 112

3. The rejection of claims 1-38 under 35 USC 112, first paragraph is maintained and claims 39-46 are rejected under 35 USC 112, first paragraph.

Applicant argues that the present specification contains more than sufficient written description to inform the skilled artisan in the art that applicants had possession of the claimed invention as required under 35 USC § 112 and that the claimed subject matter need not be described literally to satisfy the written description, as long as the description clearly conveys the invention to those skilled in the art. Applicant's argument was considered but not persuasive for the following reason.

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As stated by applicant, the claimed subject matter does not have to be described literally as long as the description in the specification clearly conveys said invention. It is the examiner's position that the present specification does not convey to the skilled artisan that applicant had possession of a selection process because there are no actual steps disclosed for said selection process. What the present specification conveys and literally teaches is treatment of an immune mediated disorder by administration of a composition comprising a gold compound and at least one corticosteroid wherein said combination exhibits synergistic action. It also discloses said immune-mediated disorder may have multiple components, such as an inflammatory and/or a cellular hyperproliferation component and that said composition can be administered to act preferably towards one or all of said components and that said selectivity is dependent on the corticosteroid utilized.

For this reason and those given in previous Office Actions, the rejection of claims 1-38 under 35 USC 112, first paragraph is maintained and claims 39-46 are rejected under 35 USC 112, first paragraph.

4. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

5. Claims 1-46 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The instant claims are indefinite because they merely recite "[a] method of selecting a treatment" without the recitation of actual steps for said selection process.

Claim Rejections - 35 USC § 102

6. Claims 29, 32, 33 and 35-38 are rejected under 35 U.S.C. 102(b) as being anticipated by Papandrea (AU-34351/89).

Papandrea teaches a composition comprising a gold compound and a corticosteroid for the treatment of local or systemic inflammatory conditions (see the entire article; especially page 6, lines 8-14 and page 11, example 2; claims 6-11 and 18). The reference teaches (a) gold compounds such as aurothimalate, aurothioglucose and auranofin (page 1, Background, lines 1-11; pages 6-8; page 11, example 2); (b) corticosteroids such as betamethasone dipropionate (page 8, lines 5-8; page 11, example 2) and (c) the synergistic effect between auranofin and corticosteroids as well as the concomitant or sequential use of the compounds (see page 17, lines 9-16). The composition and use of said composition as taught by the reference are encompassed by the instant claims.

7. Claims 29, 32, 33 and 35-38 are rejected under 35 U.S.C. 102(b) as being anticipated by Papandrea (US 5,527,779).

Papandrea teaches a composition comprising a gold compound and a corticosteroid for the treatment of local or systemic inflammatory conditions (see the entire article; especially col. 2, lines 51-54; col. 3, lines 4-11; col. 5, example 2; claims

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1-15). The reference teaches (a) gold compounds such as aurothimalate, aurothioglucose and auranofin (col. 1, lines 14-25; col. 3, lines 21-59; col. 5, example 2); (b) corticosteroids such as betamethasone dipropionate (col. 3, lines 60-63; col. 5, example 2) and (c) the synergistic effect between auranofin and corticosteroids as well as the concomitant or sequential use of the compounds (see col. 8, lines 6-17). The composition and use of said composition as taught by the reference are encompassed by the instant claims.

Claim Rejections - 35 USC § 103

8. Claims 29-46 are rejected under 35 U.S.C. 103(a) as being unpatentable over Papandrea (AU-34351/89 or US 5,527,779).

Papandrea teaches a composition comprising a gold compound and a corticosteroid for the treatment of local or systemic inflammatory conditions (see the entire disclosure of both references; especially **AU 34351**, page 6, lines 8-14 and page 11, example 2; claims 6-11 and 18; and **'779**, col. 2, lines 51-54; col. 3, lines 4-11; col. 5, example 2; claims 1-15). The reference teaches (a) gold compounds such as aurothimalate, aurothioglucose and auranofin (**AU 34351**, page 1, Background, lines 1-11; pages 6-8; page 11, example 2; and **'779**, col. 1, lines 14-25; col. 3, lines 21-59; col. 5, example 2); (b) corticosteroids such as betamethasone dipropionate (**AU 34351**, page 8, lines 5-8; page 11, example 2; and **'779**, col. 3, lines 60-63; col. 5, example 2) and (c) the synergistic effect between auranofin and corticosteroids as well as the

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concomitant or sequential use of the compounds (**AU 34351**, page 17, lines 9-16; and **'779**, col. 8, lines 6-17).

The instant claims differ from the references by reciting additional corticosteroids not exemplified by the cited prior art. However, the compounds recited by the instant invention are well known in the art, and, thus, it would have been obvious to one having ordinary skill in the art at the time of the invention to utilize any corticosteroid, including those of the instant claims, in the composition taught by Papandrea with the reasonable expectation that the composition would be useful as taught by the prior art.

Claims 30, 31 and 34 further differ from the references by reciting various routes of administration.

However, (a) Papandrea teaches the treatment of both local and systemic inflammatory conditions and (b) the preparation of a pharmaceutical formulation for use by different routes of administration is well within the level of skill of one having ordinary skill. The motivation to make different formulations would be based on the teaching by the reference of the treatment of systemic inflammatory conditions and, thus, the desire to provide a formulation that would result in optimum systemic treatment of patients in need thereof.

Other Matters

9. The rejections against the composition and method of use claims are reinstated because the patentability of said claims is dependent on the makeup composition and not the process by which said composition is obtained.

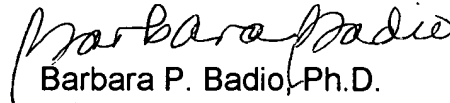
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Telephone Inquiry

10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Barbara P. Badio, Ph.D. whose telephone number is 703-308-4595. The examiner can normally be reached on M-F from 7:30am-4pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman Page can be reached on 703-308- 2927. The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-4556 for regular communications and 703-308-4556 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1235.


Barbara P. Badio, Ph.D.
Primary Examiner
Art Unit 1616

BB
August 26, 2004